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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC.	)
Plaintiffs,	)
v.	)
APOTEX INC., APOTEX CORP. and ROXANE LABORATORIES, INC.	)
Defendants.	)

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Actelion Pharmaceuticals Ltd., Gewerbestrasse 16, CH-4123 Allschwil, Switzerland ("APL") and Actelion Clinical Research, Inc., 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ 08002 ("ACR") (individually and collectively, also "Actelion"), for their Complaint against Defendants Apotex Inc., 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9 and Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326

(collectively, "Apotex"), and Roxane Laboratories, Inc., 1809 Wilson Road, Columbus, Ohio, 43228 ("Roxane") hereby allege as follows:

NATURE OF THE ACTION

1. This action concerns the fundamental right of a business to choose for itself with whom to deal and to whom to supply its products. Apotex and Roxane are seeking to force Actelion to supply them with product, turning well-settled law, not to mention basic free-market principles, on their head. Moreover, Apotex's and Roxane's demands would also require Actelion to violate its regulatory obligations. Actelion brings this case under 28 U.S.C. §§ 2201 and 2202 seeking a declaration of its rights.

2. APL obtained approval from the Food and Drug Administration ("FDA") of its New Drug Application ("NDA") for a pharmaceutical product, Tracleer. Because of potentially serious side effects associated with Tracleer, the FDA's approval was subject to Actelion's implementation of and compliance with a Risk Evaluation and Mitigation Strategy ("REMS"). The REMS places significant limitations on the sale and distribution of Tracleer, described more fully below.

3. Apotex and Roxane have demanded samples of Tracleer ***from Actelion*** so that they can develop competing generic products. Actelion has not supplied Tracleer to Apotex or Roxane. Apotex became increasingly threatening in its demands for samples, including threatening to seek the extraordinary relief of a mandatory injunction to force Actelion to sell samples to Apotex, and treble damages against Actelion unless Actelion acquiesces and supplies Tracleer to Apotex. Roxane, too, stated that it will pursue antitrust and related claims against Actelion unless its demands for Tracleer are met.

4. In short, the relief that Apotex and Roxane have threatened to seek against Actelion would be in direct contravention of not only the REMS for Tracleer, but also of the well settled legal and commercial principle that companies have the right to choose with whom they will do business and to whom they will sell their products. Indeed, as explained below, Congress has ***twice*** explicitly rejected the very thing Apotex and Roxane are demanding here—i.e., creating a legal obligation that forces a branded company such as Actelion to supply a drug product covered by a REMS to a potential generic competitor. Actelion therefore seeks a judgment by this Court determining and declaring that Actelion has no duty to deal with Apotex or Roxane and it is under no obligation to supply Tracleer to Apotex or Roxane.

PARTIES

5. Actelion Pharmaceuticals Ltd. ("APL") is a pharmaceutical company with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland. APL focuses on the discovery, development, and commercialization of innovative treatments to serve critical, unmet medical needs.

6. Actelion Clinical Research, Inc. ("ACR") is a Delaware corporation with its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ 08002. ACR is an affiliate of APL and manages the Tracleer NDA and Tracleer REMS in the United States as agent for APL.

7. Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9. Upon information and belief, Apotex Inc. is in the business of making and selling generic drug products.

8. Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is in the business of making and selling generic drug products.

9. Roxane is a Nevada corporation with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228. Upon information and belief, Roxane is in the business of making and selling generic drugs.

JURISDICTION AND VENUE

10. This case is brought under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and raises issues under Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, Section 2 of the Sherman Antitrust Act, 15 U.S.C. §2, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355-1. This Court therefore has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

11. This Court has personal jurisdiction over Apotex Inc. under N.J. Court R. 4:4-4. Apotex Inc. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Inc. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of New Jersey. In addition, Apotex Inc. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this jurisdiction.

12. This Court has personal jurisdiction over Apotex Corp. under N.J. Court R. 4:4-4. Apotex Corp. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Corp. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer

to sell, or sell pharmaceutical products throughout the State of New Jersey. In addition, Apotex Corp. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this jurisdiction.

13. This Court has personal jurisdiction over Roxane under N.J. Court R. 4:4-4. Roxane has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Roxane has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of New Jersey. Upon information and belief, Roxane is registered to do business in New Jersey and has a registered agent in New Jersey. In addition, Roxane has previously submitted to the jurisdiction of this Court.

14. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(c) because Apotex Inc., Apotex Corp., and Roxane transact business and can be found in this district. Moreover, management of the Tracleer NDA and Tracleer REMS is performed in this district by ACR from its principal place of business in Cherry Hill, New Jersey.

FACTUAL BACKGROUND

15. Actelion develops and commercializes innovative treatments to serve critical, unmet medical needs. Actelion, through a U.S. affiliate, markets in the United States a treatment for pulmonary arterial hypertension ("PAH"), a relatively rare, serious progressive disorder characterized by abnormally high blood pressure in the arteries of the lungs, making the right side of the heart work harder than is normal. APL submitted to the FDA a New Drug Application ("NDA") for its PAH treatment. Following FDA approval, Actelion launched its medicine under the proprietary name Tracleer. ACR manages the NDA and acts as APL's agent in all NDA-related issues with the FDA.

16. Tracleer is a patented drug covered by United States Patent No. 5,292,740 (the "'740 Patent"). APL is the exclusive licensee under the '740 Patent.

17. As reflected on its label, Tracleer has the potential to cause very serious side effects. In particular, Tracleer can cause serious liver damage, including in rare cases liver failure, as well as serious birth defects if taken during pregnancy. As a result of these risks, in order to obtain FDA approval for Tracleer, the FDA required APL to adopt a Risk Evaluation and Mitigation Strategy ("REMS"), a strategy to manage a known or potential serious risk associated with a drug or biological product. ACR manages the REMS program for Tracleer and acts as APL's agent in all REMS-related issues with the FDA.

18. Tracleer's FDA-mandated and approved REMS program dictates that, among other things, Tracleer will only be dispensed through pharmacies, practitioners, and health care settings that are specially certified and bound by contract to follow a strict protocol to monitor and protect patient health. The protocol includes monthly follow-up with patients to ensure that liver function testing and pregnancy testing have been completed; that only a limited supply of Tracleer can be distributed at a time; that Tracleer can only be dispensed to patients who are enrolled in the REMS program; and that certain defined patient counseling is completed regularly. Actelion's distribution of Tracleer must, and does, comply in all respects with its FDA-mandated REMS program.

19. To fulfill its REMS obligations, Actelion works only with wholesale distributors which agree to comply with Tracleer's REMS. Pursuant to the REMS program, wholesalers can only sell Tracleer to those entities which are specially certified and bound by contract to follow the Tracleer REMS protocol. Wholesale distributors of Tracleer must, and do, comply with and effectively implement the REMS program.

20. Moreover, as a result of the potential side effects, Actelion has a legitimate interest in how Tracleer is used and administered to patients. Any harm caused as a result of the potential misuse of Tracleer during testing by a generic could have a significant impact on Actelion and Tracleer's reputation and standing in marketplace. This interest exists independent of the REMS.

21. On January 21, 2011, Actelion Pharmaceuticals US, Inc. ("APUS"), an affiliate of APL, received a letter from counsel for Apotex Inc. informing Actelion of Apotex's desire to file an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Actelion's patented Tracleer drug product. Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness required in an NDA. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner) to the innovator drug product.

22. In its January 21, 2011 letter, Apotex Inc. sought samples of Tracleer from APUS so that it could complete bioequivalency studies and submit an ANDA seeking FDA approval of a generic version of Actelion's Tracleer drug product. Although the request was directed to APUS, any samples would actually be supplied by APL.

23. When Actelion did not provide samples of Tracleer, Apotex Inc. sent additional letters repeating its demands for Tracleer samples and suggesting that Actelion is required by law to fulfill Apotex Inc.'s request.

24. More recently, Apotex Inc.'s counsel sent a letter on June 26, 2012 repeating Apotex Inc.'s demands. On July 2, 2012, counsel for Actelion responded, reminding Apotex of

both the restrictions of Tracleer's REMS program and the well settled law that Actelion has the right to choose with whom it does business. Actelion declined to provide Apotex samples.

25. Counsel for Apotex Inc. responded on August 1, 2012, again demanding Tracleer samples and, this time, threatening litigation if its demands were not met. Enclosed with its letter was a draft complaint seeking, among other things, treble damages under the antitrust laws and an extraordinary mandatory injunction which, if granted, would force Actelion to provide samples to Apotex. Apotex's draft complaint alleged that Actelion is required to supply samples for the purpose of helping Apotex meet the bioequivalence testing requirements for its potential ANDA. Apotex asserted in the draft complaint that the patent-protected product Tracleer is an "essential facility."

26. On August 9, 2012, counsel for Actelion responded to Apotex Inc., reiterating Actelion's right to decide with whom it does business and its legal obligation to comply with the REMS program, which Apotex never addressed.

27. Apotex's counsel replied on August 17, 2012, stating that Apotex intended to make changes to its bioequivalence study protocol that the FDA recommended, including changes to comply with even the most basic training, patient education, and liver function testing procedures that Apotex initially omitted from its protocol. As far as Actelion is aware, Apotex has not yet made such changes. Apotex again threatened to file its antitrust complaint against Actelion if its demands were not met.

28. Actelion and Apotex attempted to resolve this dispute without the assistance of the Court, but have been unable to do so.

29. In early 2012, Roxane sent a letter to APUS demanding that Actelion sell it Tracleer tablets and indicating that Roxane was seeking samples for the purpose of filing an ANDA for a generic version of Tracleer.

30. Actelion responded on February 10, 2012, declining to provide Roxane with Tracleer tablets and maintaining its right to choose with whom it does business.

31. Counsel for Roxane again demanded Tracleer tablets by letter of August 1, 2012. The letter asserted that Actelion's denial of Roxane's demands and Actelion's acts to insure that its distributors follow the FDA-mandated REMS requirements were antitrust violations. Roxane threatened to "pursue all available options, including notifying the Federal Trade Commission and/or asserting antitrust and related claims against Actelion."

32. On August 9, 2012, counsel for Actelion responded, restating Actelion's right to make independent decisions regarding with whom it does business and how it structures its distribution system. The letter further reminded Roxane of Actelion's obligations to comply with strict distribution limitations under Tracleer's REMS, an issue Roxane never addressed.

APOTEX AND ROXANE HAVE NO BASIS TO FORCE ACTELION TO SUPPLY TRACLEER TABLETS

33. Actelion is under no duty or obligation to supply samples of Tracleer to Apotex or Roxane. There is no legal basis pursuant to which Apotex and Roxane can compel Actelion to sell Tracleer tablets. As an initial matter, their demands are inconsistent with the restrictions in the REMS for Tracleer. Because of Tracleer's potential for causing the deterioration of liver functioning and severe birth defects, the FDA, through the Tracleer REMS, requires Actelion to take specific steps to ensure the safety of patients. As described above, distribution of Tracleer is limited to pharmacies, practitioners, and health care settings that are specially certified and bound by contract to follow a strict protocol. Under the FDA-mandated REMS program,

Actelion may not distribute Tracleer to Apotex, Roxane, or to any other entity that does not specifically qualify under Tracleer's REMS. *See* Food and Drug Amendments Act of 2007, 21 U.S.C. § 355-1 (the "REMS statute").

34. Further, Actelion must ensure that any distribution through wholesalers is structured to comply with Tracleer's REMS. This requires that wholesalers follow the REMS program to the letter. Actelion's agreements with wholesalers requiring compliance with FDA-mandated restricted distribution are permissible under the antitrust laws and are justified to protect Actelion from liability relating to Tracleer's REMS. *See, e.g.*, *Sports Ctr. Inc. v. Riddell, Inc.*, 673 F.2d 786, 791 (5th Cir. 1982).

35. More fundamentally, even if sales of Tracleer were not restricted by the REMS to assure patient safety, it is well settled that Actelion, like any other company, has an independent right to choose with whom it deals. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (holding that nothing in the Sherman Act restricts a company's discretion as to parties with whom it will deal). As a corollary of this principle, Actelion also has the right ***not to*** deal with or assist a rival. *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986). As a result, courts have consistently held that companies such as Actelion are under no duty to deal with a competitor.

36. When Congress enacted the REMS statute, it did not create an independent duty to supply drugs covered by a REMS program to potential generic manufacturers or abrogate the long-standing principle that a company can choose not to assist a rival. There is no provision in the REMS statute that the owner of a drug subject to a REMS program is required to provide samples of its drug upon the request of a potential competitor.

37. To the contrary, the suggestion of such a requirement was rejected by Congress when it enacted the REMS statute. Specifically, the House version of the REMS legislation contained language providing:

> (6) BIOEQUIVALENCE TESTING - Notwithstanding any other provisions in this subsection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of [an ANDA] to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval [of an ANDA] agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing .

H.R. 2900, 110th Cong. § 901 (2007). This language was omitted from the final version of the Act, demonstrating that Congress did not impose on the drug innovator a duty to deal with a potential generic competitor. *See* 21 U.S.C. 355-1.

38. Even more recently, similar language was again rejected from the Food and Drug Administration Safety and Innovation Act. Language in the Senate amendment proposed:

> (k) DRUG DEVELOPMENT AND TESTING.— (1) In General.— Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support [an ANDA], if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has agreed to comply with the terms of the notice.

S. 3187, 112th Cong. § 1331 (May 24, 2012). This proposed language was not included in the final version of the bill, enacted on July 9, 2012.

39. The right to choose with whom one does business is subject to only a few narrow exceptions. *See Trinko*, 540 U.S. at 408. No exception is applicable here.

40. One exception might arise where the parties have a history of dealing that is terminated for no legitimate business purpose. *See Aspen Skiing Co. v. Aspen Highlands Skiing*

Corp., 472 U.S. 585 (1985). The Supreme Court has held that even this exception is "at or near the outer boundary of [Sherman Act] § 2 liability." *Trinko*, 540 U.S. at 409.

41. Actelion does not have a history of providing samples of Tracleer to Apotex or Roxane. In fact, it has never done so. Actelion's decision not to provide Tracleer samples stands on its own. Actelion has no affirmative obligation to assist Apotex or Roxane with their efforts to develop generic drugs, particularly where the generics' testing may create risk for Actelion and the Tracleer brand.

42. Another potential exception to the right to choose with whom to deal, though of questionable validity, is the so-called "essential facilities" doctrine. That doctrine requires that a monopolist provide access to a facility if an alternative to the facility is utterly infeasible; it does not impose any duty to deal merely because a lack of access to a facility is inconvenient or more expensive. *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, No. 11-cv-5328, 2012 WL 2348443, at *9-10 (2d Cir. June 21, 2012). The validity of the essential facilities doctrine has been called into question by the Supreme Court. *See Trinko*, 540 U.S. at 410 ("[The] 'essential facilities' doctrine [was] crafted by some lower courts. . . . We have never recognized such a doctrine.").

43. To the extent the essential facilities doctrine is still viable after *Trinko*, it is inapplicable here, where Apotex and Roxane are demanding samples of a patented product. Apotex and Roxane cannot use the essential facilities doctrine to subvert Actelion's patent rights by forcing it to supply Tracleer tablets. *See Eatoni*, 2012 WL 2348443, at *10 ("We agree with the district court that § 2 does not obligate [a company] to share its ***patented*** [] technology, from which [a company] derives the lawful power to exclude others' use.") (emphasis added); *Applera Corp. v. ML Research, Inc.*, 349 F. Supp. 2d 338, 348 (D. Conn. 2004) ("To find a patent an

'essential facility' to which [a company] must provide access would subvert the plain meaning and purpose of the Patent Act.").

44. Moreover, to qualify as an essential facility, access to alternatives must not be feasible. *Eatoni*, 2012 WL 2348443, at *9. But here, there are alternatives to obtaining Tracleer samples from Actelion if Apotex or Roxane intends to develop treatments for PAH. If Apotex or Roxane develops a treatment for PAH, that company can file an NDA, just as Actelion's parent company did for Tracleer, which does not require a demonstration of bioequivalence with any existing treatment. This option renders samples of Tracleer unnecessary.

45. In addition, the essential facilities doctrine does not apply where there are legitimate regulatory and business justifications for declining access, as there are here with the Tracleer REMS program. *See Illinois ex rel. Burris v. Panhandle E. Pipe Line Co.*, 935 F.2d 1469 (7th Cir. 1991) (affirming district court's finding that defendant was motivated by regulatory concerns in denying access to "essential facility"); *So. Pac. Comm. Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 1009 (D.C. Cir. 1984) (affirming judgment for defendant where denials of access to "essential facilities" were based on defendant being an enterprise regulated under a "public interest" standard); *see also MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1137 (7th Cir. 1982) ("Ordinarily, antitrust liability should not be imposed when a firm acts in compliance with its regulatory obligations.").

COUNT I
(Declaratory Relief)

46. Actelion incorporates by reference paragraphs 1 through 45 as if set forth fully above.

47. Apotex and Roxane have each repeatedly demanded from Actelion samples of Actelion's patent-protected product Tracleer for the purpose of bioequivalence testing to support

the submission of ANDAs. Actelion has resisted their demands and has continued to assert its time-honored rights to choose the parties with which it deals. Moreover, Actelion has a legal obligation to comply with the restricted distribution scheme of its REMS program, which does not allow it to provide samples of Tracleer to Apotex or Roxane.

48. Because Actelion has maintained its rights, Apotex has now threatened antitrust litigation, seeking treble damages and the extraordinary remedy of a mandatory injunction.

49. Roxane has similarly made threats to pursue antitrust litigation against Actelion.

50. Accordingly, there is currently an actual controversy between Actelion and Apotex and between Actelion and Roxane concerning Actelion's right to decline Apotex's and Roxane's demands for samples of Tracleer.

51. Pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, Actelion is entitled to a declaration of rights whereby it is declared that Actelion has no duty or obligation to provide Tracleer tablets to Apotex or Roxane.

PRAYER FOR RELIEF

WHEREFORE, Actelion respectfully requests judgment in its favor and against Apotex and Roxane as follows:

a) for a declaration that Actelion is under no duty or obligation to provide any quantity of Tracleer to Apotex;

b) for a declaration that Actelion is under no duty or obligation to provide any quantity of Tracleer to Roxane;

c) awarding such other relief as the Court deems just and proper.

September 14, 2012

Respectfully submitted,

/s/ Michelle Hart Yeary_____

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that the matters set forth in the foregoing Complaint are not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

/s/ Michelle Hart Yeary_____

Michelle Hart Yeary